

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Yuji YAMAZAKI et al.  
Title: ANTIBODY AGAINST FIBROBLAST GROWTH FACTOR-23  
Appl. No.: Not yet assigned  
Int'l Appln. No: PCT/JP03/00017  
Int'l Filing Date: January 6, 2003  
Examiner: Not yet assigned  
Art Unit: Not yet assigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of a document known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The majority of the documents listed on the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding International application. Copies of the cited documents are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and the JPO. A copy of the International Search Report setting forth the portion of each reference considered relevant by the examiner is attached along with two additional cited references.

10/500296

DT11 PCT/PTO 28 JUN 2004

Atty. Dkt. No. 081356-0218

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 CFR §1.491.

RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 28 June 2004

By S.A. Bent

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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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DT11 Rec'd PTO/PTC 28 JUN 2001  
Complete if Known

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Date Submitted: June 28, 2004

(use as many sheets as necessary)

Sheet

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of

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<b>Application Number</b>	Unassigned
<b>Filing Date</b>	Concurrently Herewith
<b>First Named Inventor</b>	Yuji YAMAZAKI
<b>Group Art Unit</b>	Not yet assigned
<b>Examiner Name</b>	Not yet assigned

Attorney Docket Number 081356-0218

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
A1		WO 02/076467			Genzyme Corporation	3/22/2002		
A2		WO 01/66595			Chiron Corporation & Kyoto University	3/7/2001		
A3		WO 01/66596			Chiron Corporation & Kyoto University	3/7/2001		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
A4		International Search Report	
A5		Takashi SHIMADA et al., "Cloning and characterization of FGF23 as a causative factor of tumor-induced osteomalacia", Proc. Natl. Acad. Sci., USA, 5/22/2001, Vol. 98, Issue 11, pp. 6500-6505.	
A6		Yuji YAMAZAKI et al., "Increased circulatory level of biologically active full-length FGF-23 in patients with hypophosphatemic rickets/osteomalacia", The Journal of Clinical Endocrinology & Metabolism, (11/2002), Vol. 87, No. 11, pp. 4957-4966.	
A7		Yuji YAMAZAKI et al, "Detection of Circulating FGF-23 by Monoclonal Antibodies Against Recombinant Human FGF-23", Journal of the American Society of Nephrology, (9/2002), Vol. 13, (Program and Abstract Issue), pg. 499A.	
A8		Takashi SHIMADA et al, "FGF-23 Is a Novel Humoral Factor Regulating Vitamin D Metabolism", Journal of the American Society of Nephrology, (9/2002), Vol. 13, (Program & Abstract Issue), pg. 28A.	
A9		Takashi SHIMADA et al., "Mutant FGF-23 responsible for autosomal dominant hypophosphatemic rickets is resistant to proteolytic cleavage and causes hypophosphatemia in vivo", Endocrinology, (8/2002), Vol. 143, No. 8 pp. 3179-3182.	
A10		Yuji YAMAZAKI et al, "Development of the ELISA System Using Monoclonal Antibodies against FGF-23 and Demonstration of Increased Plasma Concentration of FGF-23 in Tumor-Induced Osteomalacia", ENDO, 2002, The Endocrine Society's 84 <sup>th</sup> Annual Meeting, Program & Abstract, pg. 66.	
A11		Y. YAMAZAKI et al., "FGF-23 Protein is Present in Normal Plasma and Is increased in Patients with Tumor-Induced Osteomalacia", (9/2002), The Journal of Bone and Mineral Research, Vol. 17, suppl. 1, pg. 159.	

Examiner Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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